

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MONTANA
GREAT FALLS DIVISION**

ENVIRONMENTAL DEFENSE FUND;
MONTANA ENVIRONMENTAL
INFORMATION CENTER; and CITIZENS
FOR CLEAN ENERGY,

Plaintiffs,

v.

U.S. ENVIRONMENTAL PROTECTION
AGENCY; and ANDREW R. WHEELER, in
his official capacity as Administrator of
the U.S. Environmental Protection
Agency,

Defendants.

Case No. 4:21-cv-00003-BMM-JTJ

The Honorable Brian Morris,
Chief Judge

**DEFENDANTS' OPPOSITION TO PLAINTIFFS'
MOTION FOR PARTIAL SUMMARY JUDGMENT**

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INTRODUCTION

Plaintiffs, three advocacy organizations, challenge the decision by the U.S. Environmental Protection Agency (“EPA”) to immediately implement the final rulemaking entitled “Strengthening Transparency in Pivotal Science Underlying Significant Regulatory Actions and Influential Scientific Information,” 86 Fed. Reg. 469-01 (Jan. 6, 2021) (“Final Rule”), a rule that, among other things, provides internal direction to EPA employees concerning the weighing of certain scientific studies for use in future rulemakings. Plaintiffs contend that because the Final Rule allegedly limits EPA’s discretion in its consideration of certain studies, it constitutes a substantive rule that is subject to a 30-day delay in its effective date under 5 U.S.C. § 553(d). Plaintiffs further assert that EPA’s failure to delay the Final Rule’s effective date until February 5, 2021, has injured them because they are deprived of the ability to petition the agency to delay the Final Rule’s implementation. Plaintiffs argue that the immediate implementation of the rule also harms their financial, professional and organizational interests. Indeed, Plaintiffs have sought expedited briefing on their motion for partial summary judgment because they contend the relief they seek—a delay in the Final Rule’s effective date, “will be meaningful only if the Court grants it significantly in advance of th[e] February 5[, 2021] effective date.” ECF No. 7 at 1. But Plaintiffs lack standing to bring this claim, and even a cursory review of the Final Rule makes clear that it is a procedural rule that does not impose any obligations on anyone outside the

agency, let alone Plaintiffs. Plaintiffs' motion for partial summary judgment therefore should be denied.

As an initial matter, EPA has not deprived Plaintiffs of the ability to petition the agency to seek a delay of the effective date of the Final Rule. Indeed, Plaintiffs could have petitioned EPA for a delay of the effective date on January 6, 2021, right now, or at any time in the future. Pursuant to 5 U.S.C. § 553(e), “[e]ach agency shall give an interested person the right to petition for the issuance, amendment, or repeal of a rule.” Petitioning EPA for a delayed effective date of the Final Rule would plainly fall within Section 553(e)’s ambit for rule amendments. Accordingly, even if Plaintiffs possessed a procedural “right” to file a petition under 5 U.S.C. § 705 to delay the Final Rule’s effective date—a “right” that, as explained below, does not exist—the fact that Plaintiffs have decided to forgo the use of Section 553(e) to petition for a delay in the effective date is fatal to their claimed injury. Plaintiffs’ rush to court and the seeking of immediate judgment on part of their lawsuit is both unnecessary and unwarranted.

But even putting to one side their failure to take advantage of an obvious procedure to seek a delay in the Final Rule’s effective date, Plaintiffs’ contention that they have been deprived of a procedural “right” to file a petition under 5 U.S.C. § 705 is unavailing. As the Ninth Circuit has recognized, to establish Article III standing based on an alleged procedural injury, a plaintiff must establish, among other things, that the procedure was intended to protect the plaintiffs’ concrete interests. *California v. Azar*, 911 F.3d 558, 570-71 (9th Cir. 2018), cert. denied by *Little Sisters of the Poor Jeanne*

Jugan Residence v. California, 139 S. Ct. 2716 (2019). Here, Section 705 provides, in pertinent part, that “[w]hen an *agency finds* that justice so requires, it may postpone the effective date of [the] action taken by it, pending judicial review.” 5 U.S.C. § 705 (emphasis added). Nothing in that language suggests, much less supports, Plaintiffs’ contention that Congress intended to protect the concrete interest of entities like the Plaintiff, as opposed to the interests of agencies. And Plaintiffs’ other claimed harms to their alleged financial, professional, and organizational interest are equally flawed, as they are speculative, self-inflicted, and cannot be attributable to the immediate effective date of the Final Rule.

But even if Plaintiffs could overcome this fatal jurisdictional flaw, their claim fails on the merits. Simply put, EPA did not need to delay the effective date of the Final Rule because it is not a substantive rule. Plaintiffs disagree, and contend that the Final Rule is a substantive rule because it creates limits on EPA’s discretion to consider the appropriate weight to provide to certain scientific studies for future rulemakings. But even assuming arguendo that the Final Rule limits agency discretion (which, as explained below, it does not), that fact standing alone does not alter private legal rights or interests sufficient to establish a substantive rule. Otherwise, all interpretive rules, which explain agencies’ constructions of statutes they regulate and advise the public of how they are likely to apply them, would require notice-and-comment rulemaking and delayed effective dates. Yet the Administrative Procedure Act (“APA”) specifically exempts such rules from these requirements. *See* 5 U.S.C. § 553(b)(3)(A), (d).

More fundamentally, the Final Rule does not impose any legal obligations or direct consequences on Plaintiffs. For example, the rule does not apply to individual party adjudications, enforcement activities, site-specific actions, or permit proceedings. 40 C.F.R. § 30.3(b). Instead, the Final Rule simply provides instruction to EPA employees on the relative weight it should afford certain studies in certain future rulemakings. 40 C.F.R. § 30.5(c). And even then, contrary to Plaintiffs' assertions, the Final Rule provides EPA with substantial flexibility and discretion in terms of how and when the rule should apply. For example, nothing in the Final Rule precludes EPA from promulgating future rules that rely on data that it cannot independently validate. Indeed, regardless of the relative weight EPA assigns to particular studies, it must review and evaluate *all* relevant scientific studies when developing significant regulatory actions and influential scientific information. 86 Fed. Reg. at 476. And the Final Rule provides the Administrator enormous discretion to waive the rule's requirements altogether on a case-by-case basis. 40 C.F.R. § 30.7(a). For all of these reasons, the Final Rule is a procedural rule that is not subject to a 30-day delay in its effective date, and Plaintiffs' motion for partial summary judgment should be denied.

BACKGROUND

A. The Rulemaking

On January 6, 2021, EPA published the Final Rule entitled “Strengthening Transparency in Pivotal Science Underlying Significant Regulatory Actions and Influential Scientific Information,” 86 Fed. Reg. 469-01 (Jan. 6, 2021). The preamble

to the Final Rule explains that the purpose of the rule is “to increase transparency by codifying internal procedural requirements for how the EPA will consider the availability of the underlying dose-response data that it relies upon to promulgate significant regulatory actions and develop influential scientific information.” *Id.* at 474. “Dose-response” data refers to data used to characterize the quantitative relationship between the amount of dose or exposure to a pollutant, contaminant, or substance and an effect. 40 C.F.R. § 30.2. The Final Rule directs EPA “to give greater consideration to pivotal science when the underlying dose-response data are available in a manner sufficient for independent validation.” 86 Fed. Reg. at 491. The Final Rule defines “[p]ivotal science” as “the specific dose-response studies or analyses that drive the requirements or quantitative analyses of EPA significant regulatory actions or influential scientific information.” 40 C.F.R. § 30.2.

The preamble to the Final Rule explains that “[w]here underlying dose-response data in pivotal science are available, subject matter experts could independently reanalyze the data to affirm original research conclusions, check for errors, test alternative assumptions, and better understand and evaluate the implications of the uncertainty used in the original analysis.” 86 Fed. Reg. at 474. EPA concluded that independent reanalysis would enable it to “make stronger, data-driven decisions in future rulemakings or in revisions to existing rules or influential scientific information.” *Id.* This, in turn, would provide EPA the ability to “more effectively share pivotal science for external consideration and increase the opportunity for independent

validation of pivotal science by subject matter experts.” *Id.* It also would permit the public to “be able to more effectively comment, engage, and hold the EPA accountable during the development of future significant regulatory actions and influential scientific information.” *Id.*

Based on these objectives, EPA explained that it will “give greater consideration to studies where the underlying dose-response data are available in a manner sufficient for independent validation” when “promulgating significant regulatory actions or developing influential scientific information for which the conclusions are driven by the quantitative relationship between the amount of dose or exposure to a pollutant, contaminant, or substance[,] and an effect[.]” 86 Fed. Reg. at 469-70. The Final Rule also provides that EPA “shall also give greater consideration to pivotal science based on dose-response data that include[s] confidential business information, proprietary information or personally identifiable information if these data are available through restricted access in a manner sufficient for independent validation.” 40 C.F.R. § 30.5(c). The Final Rule explains that “[f]or pivotal science where there is no access to dose-response data, or access is limited, the Agency may still consider these studies but will give them lesser consideration unless the Administrator grants an exemption under § 3.07.” *Id.* Where EPA has given lesser consideration to dose-response data, it must identify the data and “provide a short description of why lesser consideration was given.” *Id.* In addition, the Final Rule sets forth nine non-exclusive factors for EPA to

consider in determining the degree of consideration to afford pivotal science for which the dose-response data are not available for independent validation. *Id.* § 30.5(d).

The preamble to the Final Rule explains that, “[c]onsistent with existing Agency practice . . . , the EPA will review and evaluate *all* relevant scientific studies when developing significant regulatory actions and influential scientific information[,]” and continue to evaluate such studies for soundness, applicability and utility, clarity and completeness, uncertainty and variability, and evaluation and review. 86 Fed. Reg. at 476 (emphasis added). The Final Rule further states that EPA “will follow best practices and rely on the highest quality, most relevant studies in determining the potential for hazard due to exposure to a pollutant, contaminant, or substance.” *Id.* at 476. Accordingly, the preamble to the Final Rule emphasizes that “EPA is not categorically excluding any studies from consideration when promulgating significant regulatory actions or developing influential scientific information[,]” and it “will continue to evaluate the quality of all relevant studies, consistent with the intended use of the information.” *Id.* at 477.

EPA further explained that where publicly available data otherwise is unavailable, alternatives may exist to obtain and validate that data. 86 Fed. Reg. at 483. For example, “[r]estricted or tiered access in this final rule means that the underlying dose-response data are available through a data sharing mechanism, such as through an agreement with the originating author or institution, access to a refined or redacted dataset that anonymizes the more sensitive portions of the analyzable dataset, a restricted access

data repository or secure data enclave[s], or some other mechanism (*e.g.*, Data Use Agreements) that allows a qualified subject matter expert access to enough data to support independent validation while still protecting sensitive information.” *Id.*

EPA acknowledged that there may be pivotal science for which the underlying dose-response data are not publicly available due to technological feasibility or that cannot be made available in a secure environment that still allows for independent analysis. 86 Fed. Reg. at 477. In that case, the Final Rule explains, EPA “may still use the pivotal science after either giving it lesser consideration or receiving an exemption from the requirements of this Rule from the Administrator” *Id.* In addition, where an environmental statute or regulation requires consideration of non-public dose-response data, the statute or regulation “would control in the event of any conflicts.” *Id.*

Id.

The Final Rule provides criteria that the EPA Administrator may consider, on a case-by-case basis, to exempt certain studies from the requirements of the rulemaking if the Administrator determines that greater consideration is warranted. 40 C.F.R. § 30.7(a). These factors include:

- (1) Technological or other barriers render sharing of the dose-response data infeasible;
- (2) The development of the dose-response data was completed or updated before January 6, 2021;
- (3) Making the dose-response data available would conflict with laws and regulations governing privacy, confidentiality, confidential business information, or national security;

- (4) A third-party has conducted independent validation of the study's underlying dose-response data through reanalysis; or
- (5) The factors used in determining the consideration to afford to the pivotal science indicate full consideration is justified.

Id. The Final Rule permits the Administrator to consider input from both EPA staff and public commenters when making a decision to grant an exemption, and requires EPA to document the rationale for exemptions to this rule in the significant regulatory action or influential scientific information. *Id.*

EPA explained that the Final Rule constitutes “a procedural rule within the scope of the EPA’s housekeeping authority[,]” and, accordingly, was exempt from the delayed effective-date requirement under 5 U.S.C. § 553(d) of the APA. 86 Fed. Reg. at 472-73.¹ The Final Rule does not regulate any entity outside of EPA. *Id.* For example, the

¹ Although Plaintiffs challenge EPA’s reliance on its housekeeping authority as a basis for promulgating the Final Rule in Count One of their Complaint, *see* ECF No. 1 ¶¶ 16-18, Plaintiffs’ motion for partial summary judgment seeks relief solely on the basis of Count Two of their Complaint. *See* ECF No. 9 at 3. Nevertheless, Plaintiffs’ contention that EPA relied “exclusively on its housekeeping authority” under the Federal Housekeeping Statute, 5 U.S.C. § 301[,] as authority for adopting the rule is incorrect. *Id.* at 13. As reflected in the Final Rule, EPA expressly acknowledged that it was not directly subject to 5 U.S.C. § 301 because it is not an “Executive department.” 86 Fed. Reg. at 471. It nevertheless gained housekeeping authority equivalent to that granted Executive Departments through the Reorganization Plan No. 3 of 1970, 84 Stat. 2086 (July 9, 1970), which created the EPA. *Id.* *See also* Authority of EPA to Hold Employees Liable for Negligent Loss, Damage, or Destruction of Government Personal Property, 32 O.L.C. 79, 2008 WL 4422366 at *4 (May 28, 2008) (concluding that the Reorganization Plan’s vesting and ancillary authority “provisions convey to the Administrator all of the housekeeping authority available to other department heads under section 301”).

Final Rule would not apply to individual party adjudications, enforcement activities, site-specific actions, or permit proceedings. *Id.* Instead, as explained in the Final Rule, “the requirements modify the EPA’s internal procedures regarding the transparency of pivotal science underlying significant regulatory actions and influential scientific information.” *Id.* at 470. EPA provided a detailed explanation for why the rulemaking constituted a procedural rule:

As the Supreme Court explained in *Chrysler Corp.*, rules of internal agency management are considered procedural rules as opposed to substantive rules under the APA. Even if there could be downstream practical effects on the voluntary behavior of outside parties and on outside parties’ interactions with the EPA, such impacts do not render this procedural rule substantive (*See American Hosp. Ass’n v. Bowen*, 834 F.2d 1037, 1051 (D.C. Cir. 1987)—“Agency rules that impose ‘derivative,’ ‘incidental,’ or ‘mechanical’ burdens upon regulated individuals are considered procedural, rather than substantive.”). As the Supreme Court explained in *Chrysler Corp.*, “the central distinction among agency regulations found in the APA is that between ‘substantive rules’ on the one hand and ‘interpretive rules, general statements of policy, or rules of agency organization, procedure, or practice on the other.’” The Supreme Court further clarified that unlike procedural rules, substantive rules have legal force and effect on individual rights and obligations, and noted that whether a rule affects individual rights and obligations is an “important touchstone” for distinguishing substantive rules from other types of rules. This final rule does not regulate the rights and obligations of any party outside of the EPA let alone have legal force and effect on them. Any incidental impacts on voluntary behavior outside of the EPA do not render this a substantive rule.

Id. at 472 (footnotes omitted).

EPA directly addressed public comments expressing concern that the rulemaking constituted a substantive rule. 86 Fed. Reg. at 472. For example, some public commenters expressed the view that the rule was substantive because it would affect

EPA's interactions with regulated parties. EPA explained that the rule does not regulate any party outside of EPA; instead, it exclusively governs EPA's internal process for determining the consideration to afford pivotal science with respect to certain action.

Id. EPA explained that the Final Rule did not require any researcher or other outside entity to provide data or models to EPA, and did not categorically exclude studies—even those where the underlying dose-response data are not available for independent validation. *Id.* EPA therefore concluded that “any incidental impact on researchers who are developing science and deciding whether to make the underlying dose-response data available is negligible.” *Id.*

EPA also addressed public commenters who contended the rule was substantive because “it imposes burdens on scientists who endeavor to have their research considered by the EPA when it makes regulatory decisions or develops influential scientific information.” 86 Fed. Reg. at 472. As EPA explained:

[P]rocedural rules do not alter the rights or interests of parties but they “may alter the manner in which the parties present themselves or their viewpoints to the agency,” without thereby becoming substantive rules (*James A. Hurson Assocs. v. Glickman*, 229 F.3d 277, 280 (D.C. Cir. 2000)). If researchers want to increase the likelihood that their studies receive greater consideration by the EPA, they may take steps to ensure that the underlying dose-response data are available to the greatest extent possible. But any such response to this final rule would be purely voluntary. It is not required by this rule.

Id.

Based on EPA's determination that the Final Rule was a procedural rule, it concluded that the rule was exempt from both the notice-and-comment and delayed

effective-date requirements under 5 U.S.C. § 553(a)(2), (b)(A), (d), of the APA. 86 Fed. Reg. at 472. EPA nevertheless voluntarily sought public comment on the proposed rule “because it believed that the information and opinions supplied by the public would inform the Agency’s views.” *Id.*

Finally, the preamble to the Final Rule explains that EPA intends to issue implementing guidelines in the future that would help to execute the rule consistently across programs, and that such guidance “may include the process for designating key studies as pivotal science, documenting the availability of dose-response data, and requesting an Administrator’s exemption.” *Id.* at 471.

B. Complaint and Motion for Partial Summary Judgment

Plaintiffs filed their two-count Complaint on January 11, 2021. In Count One, Plaintiffs contend that the Final Rule is unlawful under the APA because EPA improperly relied upon the Federal Housekeeping Statute, 5 U.S.C. § 301, in promulgating the rule. ECF No. 1 ¶¶ 16-18. In Count Two, Plaintiffs allege that EPA’s decision to make the Final Rule effective on publication violates 5 U.S.C. § 553(d) because it is a substantive rule and none of the exceptions to section 553(d) apply. *Id.* ¶¶ 19-24. As relief, Plaintiffs seek the following: (1) a declaration that EPA lacked the authority to promulgate the Final Rule; (2) an injunction to set aside the Final Rule; (3) a declaration that the Final Rule violates section 553(d) because its effective date is not at least 30 days after its publication in the Federal Register; and (4) a declaration that

the Final Rule's effective date is 30 days after the date that the rule was published in the Federal Register. *Id.* Prayer for Relief.

Plaintiffs filed a motion for partial summary judgment simultaneously with its Complaint. ECF No. 9. Plaintiffs' motion focuses only on Count Two. Plaintiffs contend in their motion that they possess Article III standing to challenge the effective date of the Final Rule; that the Final Rule substantively restricts EPA's discretion and thus is a substantive rule subject to the APA's 30-day notice requirement; and that the agency has not demonstrated good cause to forgo the 30-day notice requirement. *See generally id.*

ARGUMENT

Plaintiffs lack standing to challenge EPA's decision to immediately implement the Final Rule because they have failed to identify a legally cognizable injury that is traceable to EPA's decision. And even if Plaintiffs possessed standing, their argument fails on the merits. The Final Rule is a procedural rule that is exempt from the APA's 30-day delayed effective date requirement contained in 5 U.S.C. § 553(d). Accordingly, Plaintiffs' contention that EPA failed to comply with Section 553(d) lacks merit, and their motion for partial summary judgment should be denied.

I. PLAINTIFFS LACK ARTICLE III STANDING TO CHALLENGE EPA'S DECISION NOT TO DELAY THE FINAL RULE'S EFFECTIVE DATE

Plaintiffs, all advocacy organizations, allege that they have been injured by EPA's decision not to delay the Final Rule's effective date in two ways—it would strip

them of their claimed right to petition the incoming administration to postpone the rule’s effective date under 5 U.S.C. § 705, and it would harm their financial, professional and organizational interests. ECF No. 9 at 29. Neither of these claimed injuries is sufficient to establish Article III jurisdiction.

“[S]tanding is an essential and unchanging part of the case-or-controversy requirement of Article III.” *Lujan v. Defs. of Wildlife*, 504 U.S. 555, 560 (1992). As an element of “the irreducible constitutional minimum of standing[,]” a “plaintiff must have suffered an ‘injury in fact’—an invasion of a legally protected interest which is (a) concrete and particularized, and (b) actual or imminent, not conjectural or hypothetical[.]” *Id.* (citations and quotation omitted). A particularized injury is one that affects the plaintiff in “a personal and individual way[.]” whereas a concrete injury must be ““*de facto*; that is, it must actually exist.” *Spokeo, Inc. v. Robins*, 136 S. Ct. 1540, 1548 (2016). “A federal court’s jurisdiction therefore can be invoked only when the plaintiff himself has suffered some threatened or actual injury resulting from the putatively illegal action.” *Warth v. Seldin*, 422 U.S. 490, 499 (1975) (citation omitted). An organizational plaintiff—like Plaintiffs here—must establish that it has either organizational standing based on alleged “injury to itself” or representational standing based on “alleg[ations] that its members, or any one of them, are suffering immediate or threatened injury as a result of the challenged action of the sort that would make out a justiciable case had the members themselves brought suit.” *Id.* at 511.

Because the Plaintiffs are moving for partial summary judgment, “mere allegations of injury are insufficient. Rather, a plaintiff must establish that there exists no genuine issue of material fact as to justiciability or the merits.” *Dep’t of Commerce v. U.S. House of Representatives*, 525 U.S. 316, 329 (1999); *see also Cent. Delta Water Agency v. United States*, 306 F.3d 938, 947 (9th Cir. 2002). Plaintiffs have not met this burden, and accordingly this Court should deny their motion.

A. Plaintiffs’ alleged deprivation of the ability to petition EPA to postpone the rule’s effective date is not a cognizable injury.

The principal argument in Plaintiffs’ motion for partial summary judgment is that EPA’s decision to immediately implement the Final Rule violated the APA. *See generally* ECF No. 9. Even assuming that a 30-day delay in the rule’s effective date was required under the APA—which it was not, *see infra* Section II—this alleged procedural harm cannot, on its own, sustain the Court’s subject matter jurisdiction.

“[D]eprivation of a procedural right without some concrete interest that is affected by the deprivation—a procedural right *in vacuo*—is insufficient to create Article III standing.” *Summers v. Earth Island Inst.*, 555 U.S. 488, 496 (2009); *accord Wilderness Soc’y, Inc. v. Rey*, 622 F.3d 1251, 1255 (9th Cir. 2010); *Glasser v. Nat’l Marine Fisheries Serv.*, 360 F. App’x 805, 806 (9th Cir. 2009); *Clatskanie Peoples Util. Dist. v. Bonneville Power Admin.*, 330 F. App’x 637, 638 (9th Cir. 2009). Irrespective of any procedural “right” under the APA to a delayed effective date or to have the opportunity to request a later effective date, “the requirement of injury in fact is a hard

floor of Article III jurisdiction that cannot be removed by statute.” *Summers*, 555 U.S. at 497. “[T]he injury-in-fact requirement” is not satisfied merely “by congressional conferral upon *all* persons of an abstract, self-contained, noninstrumental ‘right’ to have the Executive observe the procedures required by law.” *Lujan*, 504 U.S. at 573. Rather, to create standing a procedural injury must “impair a separate concrete interest[.]” *Id.* at 572.

The Ninth Circuit accordingly rejects the notion that an injury can be “sufficiently concrete and particularized” where “the harm was the loss of the opportunity to comment” without an “assert[ion] that any *specific* injury will occur[,]” because such a “finding cannot be squared with the Supreme Court’s analysis in *Summers*.¹” *Wilderness Soc’y*, 622 F.3d at 1257-58 (citation omitted, emphasis added). Plaintiffs have identified no concrete injury that they contend will ensue as a result of the lack of the opportunity to request a later effective date for the Final Rule. Plaintiffs’ challenge is instead to a “regulation in the abstract . . . apart from any concrete application that threatens imminent harm to [their] interests[,]” and is therefore inadequate to establish Article III injury. *Summers*, 555 U.S. at 494; *Sequoia Forestkeeper v. Tidwell*, 847 F. Supp. 2d 1217, 1231 (E.D. Cal. 2012) (noting that Article III standing requires, *inter alia*, that “the alleged injury must be tied to a *specific application* of the challenged regulations” (emphasis added)).

More fundamentally, contrary to Plaintiffs’ assertion, they have not lost the opportunity to petition EPA to reconsider the effective date of the Final Rule (or any

other aspect of the rule, for that matter). Pursuant to 5 U.S.C. § 553(e), “[e]ach agency shall give an interested person the right to petition for the issuance, amendment, or repeal of a rule.” 5 U.S.C. § 553(e). The petitioning of an agency for a delayed effective date would plainly fall within Section 553(e)’s ambit for rule amendments, and the fact that Plaintiffs have decided to forgo this procedural avenue is fatal to their claimed injury.

Rather than identify a concrete, specific injury resulting from EPA’s decision to immediately implement the Final Rule, Plaintiffs advance a novel and legally unsupported proposition: that section 553(d) of Title 5 of the U.S. Code is intended to protect Plaintiffs’ concrete interests in exercising their “right” to file a petition under 5 U.S.C. § 705 to seek a delay of the Final Rule’s effective date. ECF No. 9 at 31. As an initial matter, it is not apparent that the first sentence of Section 705, which Plaintiffs rely upon to support their claimed “right,” is even intended to protect the interests of Plaintiffs as opposed to agencies. *See California v. Azar*, 911 F.3d at 570-71 (holding that to establish an Article III injury the procedures in question must be designed to protect concrete interests); *Ctr. for Law and Educ. v. Dep’t of Educ.*, 396 F.3d 1152, 1157 (D.C. Cir. 2005) (holding that plaintiffs lacked standing because they could not show that the claimed procedural rights were designed to protect their interests). Section 705 provides, in pertinent part: “When an *agency finds* that justice so requires, it *may* postpone the effective date of [the] action taken by it, pending judicial review.” 5 U.S.C. § 705 (emphases added). The focus on the agency suggests that this provision

is not intended to protect the interests of Plaintiffs but rather is intended for the benefit of agencies.² And even if a “right” existed to file a petition under Section 705, that itself is not a concrete interest but merely another procedural right. Plaintiffs have cited to no authority that standing can be established based on a procedural right that does not directly protect a concrete interest but only another procedural right. Accordingly, Plaintiffs may not base standing upon the alleged deprivation of their ability to request an extension of the Final Rule’s effective date.

B. Plaintiffs’ alleged harms to their financial, professional and organizational interests are speculative and self-inflicted.

Plaintiffs next contend that by depriving them of the ability to seek a postponement of the Final Rule’s effective date, they are facing harm to their financial, professional and organizational interests. ECF No. 9 at 32-39. Any alleged harms Plaintiffs contend they are suffering to their economic, professional or organizational interests are completely speculative and self-inflicted, and cannot be attributed to the immediate effective date of the Final Rule.

The Supreme Court has soundly rejected the notion that a plaintiff may establish standing based on measures they have taken to avoid future, speculative harm. *Clapper*

² In contrast to Section 705, other provisions of the APA do appear to be intended to protect the interests of members of the public. *See, e.g.*, 5 U.S.C. § 553(e) (“Each agency shall give an interested person the right to petition for the issuance, amendment, or repeal of a rule”); *id.* § 553(c) (“the agency shall give interested persons an opportunity to participate in the rule making[.]”).

v. *Amnesty Int'l*, 568 U.S. 398, 415 (2013). In *Clapper*, plaintiffs seeking to contest the constitutionality of suspected Government surveillance of their communications attempted to establish their standing on the basis that the risk of surveillance had forced them to take “costly and burdensome measures to protect the confidentiality of their communications[,]” including forbearance from certain communications altogether. 568 U.S. at 415. The Supreme Court rejected this theory of injury, holding that the plaintiffs could not “manufacture standing merely by inflicting harm on themselves based on their fears of hypothetical future harm that is not certainly impending.” *Id.* at 416. “Because [the plaintiffs] d[id] not face a threat of certainly impending” surveillance, the costs they incurred to avoid surveillance were “self-inflicted injuries” attributable only to their own subjective fears, and as such were “insufficient to create standing.” *Id.* at 417-18.

Here, any alleged financial, business or organizational harms Plaintiffs may have suffered cannot be fairly traced to the immediate effective date of the Final Rule, but rather their independent decisions based on their speculation as to how EPA may implement the Final Rule in the future. For example, Plaintiffs contend that certain of Environmental Defense Fund (“EDF’s”) members are research scientists, and the Final Rule threatens their interests by placing them “in a difficult double bind.” ECF No. 9 at 32. Plaintiffs claim that if they decline to conduct research that relies on dose-response data that can be independently verified, they will lose access to grant funding. *Id.* And if they attempt to conform their research to the rule to ensure it receives the

weight it is due, they will face “the risk of alienating research-subject communities and the expense of reworking their research agendas to try to develop rule-compliant methods.” *Id.*

EPA addressed this precise issue in the Final Rule, and explained that the Final Rule did not require any researcher or other outside entity to provide data or models to EPA, and did not categorically exclude studies—even those where the underlying dose-response data are not available for independent validation. 86 Fed. Reg. at 472. EPA further explained that “[i]f researchers want to increase the likelihood that their studies receive greater consideration by the EPA, they may take steps to ensure that the underlying dose-response data are available to the greatest extent possible. But any such response to this final rule would be purely voluntary. It is not required by this rule.” *Id.*

Plaintiffs contend that the immediate effective date of the rule may diminish access to research funding by the National Institute of Health (“NIH”), which will in turn impose “immediate and far-reaching financial consequences on EDF members who are research scientists.” ECF No. 9 at 32-33. Plaintiffs’ speculation about how third parties such as NIH may respond to a particular grant request in the future is legally insufficient to establish Plaintiffs’ standing. *Washington v. Dep’t of Health & Human Servs.*, No. C20-1105JLR, 2020 WL 5095467, at *7 (W.D. Wash. Aug. 28, 2020) (rejecting as speculative state’s claim of increased costs and other economic harms

resulting from increased discrimination allegedly caused by regulation's definition of "sex").

Indeed, Plaintiffs' alleged harms have nothing to do with their claim that EPA decided to immediately implement the Final Rule. Instead, Plaintiffs' allegations are based on a chain of speculative assumptions: that EPA in the future (and in a new Administration) will propose a rulemaking that implicates the research of one of Plaintiffs' members and that implicates the Final Rule (and is not subject to a separate environmental statute that requires consideration of such data); that said research relies upon dose-response data that cannot be independently verified; that NIH decides to modify its grants to Plaintiffs' members on the basis of the future application of the Final Rule; that EPA decides to give that study less weight than it otherwise would because of the Final Rule; the Administrator decides not to waive the data availability requirement for the proposed rule at issue, as he is permitted to do on a case-by-case basis; and that the future rulemaking is somehow materially impacted by the lesser weight EPA gives to that particular data. Plaintiffs' chain of speculative future events and suggestion that their self-inflicted injuries are fairly traceable to EPA's immediate effective date are foreclosed by *Clapper*.

Plaintiffs' claimed harm to their professional and organizational interests fare no better. Plaintiffs' allegations concerning professional harm are simply a repackaging of their claimed financial harm. Plaintiffs assert that "EDF members have professional interests in conducting high-quality scientific research that can inform all levels of EPA

decision-making[,]” and that the Final Rule “threatens these concrete interests” because “the rule makes it less likely that researchers’ work will achieve one of the most important measures of scientific impact—*influencing significant EPA decision-making.* ECF No. 9 at 36-37. Similarly, Plaintiffs contend that the organizations “independently have concrete interests in EPA’s full consideration of the best available science as a basis for significant regulatory actions and influential scientific information.” *Id.* at 37. They further allege that their members “also have concrete health, safety, and recreational interests of their own” in ensuring that “EPA[’s] actions are based on the best available science and accord that science its proper weight[.]” *Id.* at 38. Plaintiffs also claim that they will face “immediate financial expenses in conforming their research agendas to the rule” *Id.* at 38. For the reasons discussed above, the Final Rule does not require Plaintiffs or its members to take any actions, and each of these additional claimed harms are based on the same speculative chain of events, including the data that EPA may or may not consider in some heretofore unidentified future rulemaking.

Because Plaintiffs cannot establish Article III standing based on their claimed injuries, which are not traceable to the immediate effective date of the Final Rule, their motion for partial summary judgment must be denied.

II. THE FINAL RULE IS A PROCEDURAL RULE

The APA generally requires a 30-day period after publication of a rule before the rule can become effective for substantive rules, but “interpretative rules, general

statements of policy, or [other] rules of agency organization, procedure, or practice” are explicitly exempt from this requirement. 5 U.S.C. § 553(b)(3)(A) (providing that “rules of agency organization, procedure, or practice” are exempt from the general APA rulemaking requirements). The Ninth Circuit defines “rules of agency organization, procedure, or practice”—referred to in the case law as “procedural rules,” *Erringer v. Thompson*, 371 F.3d 625, 630, 633 n.15 (9th Cir. 2004)—as rules that “extend[] to ‘technical regulation of the form of agency action and proceedings.’” *S. Cal. Edison Co. v. FERC*, 770 F.2d 779, 783 (9th Cir. 1985) (quoting *Pickus v. U.S. Bd of Parole*, 507 F.2d 1107, 1113 (D.C. Cir. 1974)). This exception was provided in the APA to “ensure that agencies retain latitude in organizing their internal operations.” *Batterton v. Marshall*, 648 F.2d 694, 708 (D.C. Cir. 1980).

As the D.C. Circuit explains, a procedural rule “covers agency actions that do not themselves alter the rights or interests of parties, although it may alter the manner in which the parties present themselves or their viewpoints to the agency.” *JEM Broad. Co., Inc. v. FCC*, 22 F.3d 320, 326 (D.C. Cir. 1994) (citation omitted). In this regard, agency rules that structure the manner in which the agency applies substantive standards generally qualify as procedural rules. See *James V. Hurson Assocs., Inc. v. Glickman*, 229 F.3d 277, 281 (D.C. Cir. 2000). Even when a procedural rule has “substantive impact” on parties before an agency, it is nonetheless exempt from this requirement. *S. Cal. Edison Co.*, 770 F.2d at 782-83; see also *James V. Hurson Assocs.*, 229 F.3d at 281 (noting that procedural rule remains exempt from notice-and-comment

even when it is “especially burdensome” on “regulated parties”). Similarly, policy statements that create rebuttable presumptions, even where they significantly impact regulated parties, are not substantive rules so long as they “leave[] the administrator free to exercise his informed discretion.”” *Panhandle Producers & Royalty Owners Assoc. v. Economic Regulatory Admin.*, 822 F.2d 1105, 1110 (D.C. Cir. 1987) (quoting *Brock v. Cathedral Bluffs Shale Oil Co.*, 796 F.2d 533, 537 (D.C. Cir. 1986)).

Plaintiffs contend that the Final Rule is a substantive rule because it “creates a limit on the agency’s discretion by adding new provisions to the Code of Federal Regulations that limit, for the first time, the weight that the agency is authorized to afford to studies that rely on non-public data.” ECF No. 9 at 17. Plaintiffs observe that the Final Rule provides that EPA “shall” give greater consideration to pivotal science where the underlying dose-response data are available in a manner sufficient for independent validation, and that where such data is unavailable, the agency “will give” the data less consideration. *Id.* (emphasis omitted). And although Plaintiffs acknowledge that the Final Rule permits the Administrator to grant an exemption to the requirement on a case-by-case basis, they contend that the rule forecloses EPA “from considering the studies the rule targets on an equal footing with other available evidence.” *Id.* at 17-18.

Plaintiffs’ assertion is legally meritless because “creat[ing] limits on agency discretion” does not, standing alone, alter rights or legal interests. Otherwise, interpretative rules—*i.e.*, those that explain agencies’ “construction of the statutes and

rules which it administers[,]” *Shalala v. Guernsey Mem'l Hosp.*, 514 U.S. 87, 99 (1995) (citation omitted), and “advise the public’ of how the agency understands, and is likely to apply, its binding statutes[.]” *Kisor v. Wilkie*, 139 S. Ct. 2400, 2420 (2019) (citation omitted)—would require notice-and-comment rulemaking and a delayed effective date. The APA specifically exempts such rules from both the notice-and-comment and delayed effective date requirements, 5 U.S.C. § 553(b)(3)(A), (d). Thus, Plaintiffs’ characterization of the operation of the Final Rule—even if it were true—could not establish that the rule comprises a substantive rule.

Plaintiffs primarily rely upon the D.C. Circuit’s decision in *CropLife Am. v. EPA*, 329 F.3d 876 (D.C. Cir. 2003), in support of their argument that the Final Rule is a substantive rule. But *CropLife* is inapposite. In *CropLife*, EPA issued a press release that announced that it would no longer rely upon third-party human studies in evaluating the safety of pesticides in connection with its regulatory decision-making. 329 F.3d at 881. The D.C. Circuit held that the press release constituted a substantive rule subject to notice-and-comment requirements because it was “binding on petitioners, who are now barred from relying on third-party human studies (even in cases where such studies formerly were approved), and is binding on the agency because EPA has made it clear that it simply ‘will not consider’ human studies.” *Id.* The D.C. Circuit emphasized that EPA, through its press release, “has enacted a firm rule with legal consequences that are binding on both petitioners and the agency[.]” *Id.* at 882.

Here, the Final Rule does not impose any legal obligations or direct consequences on Plaintiffs and does not regulate any entity outside of EPA. 86 Fed. Reg. at 472. For example, the Final Rule would not apply to individual party adjudications, enforcement activities, site-specific actions, or permit proceedings. 40 C.F.R. § 30.3(b). Instead, as explained in the Final Rule, “the requirements modify the EPA’s internal procedures regarding the transparency of pivotal science underlying significant regulatory actions and influential scientific information.” 86 Fed. Reg. at 470 (footnote omitted). Indeed, the Final Rule simply provides instruction to EPA employees on the relative weight it should afford certain studies in certain rulemakings. 40 C.F.R. § 30.5(c). But even then, it does not require EPA employees to reach a particular result in any particular rulemaking. The Final Rule explains that, regardless of weighing, “EPA will review and evaluate *all* relevant scientific studies when developing significant regulatory actions and influential scientific information[,]” and continue to evaluate such studies for soundness, applicability and utility, clarity and completeness, uncertainty and variability, and evaluation and review. 86 Fed. Reg. at 476 (emphasis added). For example, nothing in the Final Rule precludes EPA from promulgating a new rule that relies on dose-response data that it cannot independently validate. And the Final Rule provides substantial discretion on the part of the Administrator to waive the rule’s requirements, on a case-by-case basis, including when “full consideration is justified.” 40 C.F.R. § 30.7(a)(5); *see Panhandle Producers*, 822 F.2d at 1110 (holding that policy statements that create rebuttable presumptions, even

where they significantly impact regulated parties, are not substantive rules so long as they leave the administrator free to exercise informed discretion). Accordingly, the Final Rule exudes substantial discretion on both EPA employees in *how* to consider the relative weight of various studies in promulgating rules, as well as on behalf of the Administrator in terms of whether to apply such weighing in a particular matter.³ The Final Rule thus falls squarely within the Ninth Circuit's definition of a procedural rule.

See S. Cal. Edison Co., 770 F.2d at 783; *Rivers v. U.S. Dep't of Interior*, No. C05-2086P, 2006 WL 2841929, at *4 (W.D. Wash. Oct. 3, 2006) (relying on *Southern California Edison* and finding a rule procedural when it "establish[ed] procedures for conducting

³ *Neighborhood TV Co., Inc. v. FCC*, 742 F.2d 629 (D.C. Cir. 1984), also undercuts Plaintiffs' claim that the Final Rule is a substantive rule. In that case, the D.C. Circuit recognized that "[c]ourts have not had an easy time deciding whether particular agency rules were 'procedural' or 'substantive.'" *Neighborhood TV*, 742 F.2d at 637. Nevertheless, the court explained that "[a] useful articulation of the exemption's critical feature is that it covers agency actions that do not themselves alter the rights or interests of parties, although it may alter the manner in which the parties present themselves or their viewpoints to the agency." *Id.* (citation omitted). The D.C. Circuit concluded that the FCC's decision to freeze all opposed translator applications, and to later reorder processing of applications according to a tiered, rather than a first-filed processing system, constituted a procedural rather than a substantive rule. *Id.* The court noted that the broadcaster's ultimate interest in the FCC proceedings was the grant of television translator licenses, and the freeze and processing reorder decisions only incidentally affected those interests by delaying consideration of the application and subjecting the application to increased competition with qualified applicants. *Id.* The D.C. Circuit held that such an interim processing rule was procedural rather than substantive. *Id.* at 638. Similarly, the Final Rule's instruction concerning the EPA's relative weighing of certain studies does not alter any rights or interests of any parties, and, at most, only incidentally affects the interests of Plaintiffs.

the agency trial-type hearings” including “rules for pre-hearing discovery, hearing procedures, and the like”).

Plaintiffs’ reliance on *Batterton v. Marshall*, 648 F.2d 694 (D.C. Cir. 1980), ECF No. 9 at 18, is equally unavailing. Indeed, *Batterton* supports the conclusion that the Final Rule is a procedural rule. In that case, the D.C. Circuit held that a Department of Labor (“DOL”) procedure changing its methods for determining unemployment rates constituted a substantive rule subject to notice-and-comment requirements where such rates were used to create disbursements for training and job programs. The D.C. Circuit explained that substantive rules “grant rights, impose obligations, or produce other significant effects on private interests.” *Id.* at 701-02. Procedural rules, on the other hand, “express the agency’s intended course of action, its tentative view of the meaning of a particular statutory term, or internal house-keeping measures organizing agency activities.” *Id.* at 702. The D.C. Circuit explained that the distinction between substantive and procedural rules is whether they foreclose alternative course of action or conclusively affect rights of private parties. *Id.* The D.C. Circuit held that DOL’s procedure constituted a substantive rule because the methodology for determining unemployment rates was a “critical factor in an otherwise inflexible statutory formula for allocating monies.” *Id.* at 705. The court observed that DOL’s methodology “conclusively determines the unemployment statistics which trigger the emergency job program allocations.” *Id.* at 706. It further held that the statistical methodology “leaves no room for further exercise of administrative discretion.” *Id.*

The D.C. Circuit noted that the “critical feature” of a procedural rule is that it covers agency actions that “do not themselves alter the rights or interests of parties, although it may alter the manner in which the parties present themselves or their viewpoints to the agency.” *Id.* 707. The court accordingly held that, as a result of DOL’s newly announced methodology, the recipients of emergency job program monies are subject to a new method for determining the one undefined variable in the statutory allocation formula, which directly affect the rights and interests of private parties. *Id.*

Here, nothing in the Final Rule forecloses alternative courses of action or conclusively affects the rights of private parties. As discussed above, the Final Rule contains substantial flexibility to agency employees to consider how certain dose-response studies should be considered in formulating future rulemakings, and further provides the Administrator enormous flexibility to determine whether the rule should apply in any particular future rulemaking, on a case-by-case basis. The Final Rule does not predetermine the result of any future rulemaking. Indeed, unlike the statutory allocation formula at issue in *Batterton*, which would have been directly impacted by DOL’s change in methodology—and which then would directly impact the amount of money received by job program recipients—Plaintiffs in this case cannot even identify a single future regulation that is negatively affected by the potential relative weighing contemplated by the Final Rule. In short, *Batterton* supports the position that the Final Rule is a procedural, rather than substantive, rule.

Finally, notwithstanding Plaintiffs' argument to the contrary, ECF No. 9 at 18, nothing in the Final Rule indicates that it has the force of law required to constitute a substantive rule. The Ninth Circuit has held that there are three circumstances when a rule has the force of law and is therefore a substantive rule subject to the APA's requirements:

- (1) when, in the absence of the rule, there would not be an adequate legislative basis for enforcement action;
- (2) when the agency has explicitly invoked its general legislative authority; or
- (3) when the rule effectively amends a prior [substantive] rule.

Hemp Indus. Ass'n v. DEA, 333 F.3d 1082, 1087 (9th Cir. 2003) (quoting *Am. Mining Congress v. Mine Safety & Health Admin.*, 995 F.2d 1106, 1112 (D.C. Cir. 1993)); *see also Disabled Am. Veterans v. Sec'y of Veterans Affairs*, 859 F.3d 1072, 1077 (Fed. Cir. 2017).

None of these three circumstances applies here. The first circumstance is met only when a statute would have no effect without an agency policy to give it content. *See Erringer*, 371 F.3d at 630; *Am. Mining Congress*, 995 F.2d at 1109. This circumstance does not apply here because EPA promulgated the Final Rule pursuant to the housekeeping authority it received under the Reorganization Plan No. 3 of 1970. 86 Fed. Reg. at 471. By definition the housekeeping authority has no effect on third parties and simply provides a basis for EPA to promulgate regulations that govern its internal affairs. And the Final Rule does not apply to individual party adjudications, enforcement activities, site-specific actions, or permit proceedings. 40 C.F.R. § 30.3(b).

The second circumstance does not apply because EPA does not possess general legislative authority; accordingly the Final Rule was not promulgated pursuant to any such authority. The third circumstance does not apply because, as Plaintiffs concede, ECF No. 9 at 17, there has never been a legislative rule governing the exercise of the weight EPA should afford to certain scientific studies, so the Final Rule could not have amended a prior substantive rule. Because none of these three circumstances apply, the Final Rule does not have the force of law and does not constitute a substantive rule. As a procedural rule, the Final Rule properly may become immediately effective, and Plaintiffs' motion for partial summary judgment should be denied.⁴

CONCLUSION

For the foregoing reasons, Defendants respectfully request that the Court deny Plaintiffs' motion for partial summary judgment.

⁴ Although Plaintiffs spend considerable pages arguing that Section 553(d)(3)'s good cause standard for dispensing with a delay in publication should not apply in this case, ECF No. 9 at 19-28, the Court need not reach this issue. If the Court agrees with Defendants that the Final Rule is a procedural rule, then Section 553(d)(3) does not apply. And if the Court disagrees with Defendants and concludes that the Final Rule is a substantive rule, then the rule would lack a legal basis because EPA promulgated the rule pursuant to its housekeeping authority, which only permits the promulgation of procedural rules.

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CERTIFICATE OF COMPLIANCE

Pursuant to Local Rule 7.1(d)(2)(E), undersigned counsel hereby certifies that this brief is 8,337 words, excluding the caption, certificate of compliance, table of contents and authorities.

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